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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,782	04/15/2004	Bernardus Petrus Hubertus Peeters	2183-4646.2US	7153

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EXAMINER	
HURT, SHARON L	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
10/10/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/824,782	PEETERS ET AL.	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *6-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 9-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 10, 2007 has been entered.

Response to Amendment

The amendments to the claims filed September 10, 2007 has been entered. Claims 1 and 2 are currently amended.

Status of the Claims

Claims 1-16 are pending. Claims 6-8 have been withdrawn. Claims 1-5 and 9-16 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 102

The rejection of claims 1-5 and 9-16 under 35 U.S.C. 102(b) as being anticipated by Taylor et al. (Journal of Virology, Apr. 1990, Vol. 64, No. 4, pages 1441-1450) **is withdrawn**. Applicant's arguments filed September 10, 2007 have been fully considered and they are persuasive.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (Journal of Virology, Apr. 1990, Vol. 64, No. 4, pages 1441-1450).

The claimed invention is drawn to a method for assigning an animal to a group of: (a) animals infected with wild-type Newcastle Disease Virus (NDV) or vaccinated with a first vaccine comprising unmodified mesogenic or lentogenic NDV strain of NDV; (b) animals not infected with or vaccinated against NDV and animals or vaccinated with a vaccine comprising an infectious copy of an avian paramyxovirus at least partially derived from NDV obtained by transfecting an avian paramyxovirus cDNA comprising an amino acid sequence corresponding to the 5'-terminal end of the genome to generate an infectious copy, wherein the copy encodes one or more viral proteins having a modification relative to wild-type, unmodified mesogenic or lentogenic NDV strain, wherein the method comprises providing a population of animals wherein one or more said animal has been vaccinated with said second vaccine; taking at least one sample from the animal and analyzing it to determine the presence of antibodies directed against an epitope or marker expressed by an animal infected with wild-type NDV or vaccinated with said first vaccine of unmodified NDV, but not by an animal vaccinated with said second vaccine; correlating the presence of antibodies directed againstan epitope or marker expressed by

an animal infected with wild-type NDV or vaccinated with said first vaccine, but not by an animal vaccinated with said second vaccine, with the animal not having been immunized with said second vaccine assigning the animal to a group, wherein said antibodies are directed against an epitope or marker expressed by wild-type or unmodified NDV, but not by said second vaccine are directed against an epitope on a hemaglutinin-nueraminidase (HN) or fusion (F) protein of NDV, wherein the modification is in a viral nucleocapsid (N), phosphoprotein (P) or large (L) protein, wherein the animal is a chicken, where said NDV is lentogenic, wherein said modification comprises a modification of a structural protein, a HN protein, or a matrix (M) protein, a modified protease cleavage site, wherein said cleavage site is a protease cleavage site of the cleavage site of the fusion protein, wherein said infectious copy of an avian paramyxovirus further comprises a nucleic acid encoding a heterologous antigen, wherein said heterologous antigen is derived from a poultry pathogen.

Taylor teaches a method of detecting NDV F protein in samples from chickens that were vaccinated with lentogenic or mesogenic strains of NDV and chickens infected with wild-type NDV (page 1446 and 1448, Discussion). Taylor also teaches that cleavage of the F protein is important in determining the pathogenicity of the NDV strain and the amino acid sequence at the cleavage site is therefore critical in determining the virulence of the NDV strain (page 1444, 2nd column). Taylor further teaches that a comparison of the sequence differences can differentiate the avirulent strains from the virulent strains therefore distinguishing the vaccinated from the unvaccinated chickens and wild-type NDV from unmodified or lentogenic strains of NDV (page 1448).

Taylor teaches that there are less virulent strains, which would be difficult to detect by obvious respiratory symptoms in the birds, therefore there is a need to detect infections by these less virulent strains, to cull these birds from the populations. The art also teaches the fusion protein expressed in the vaccine is immunogenic and therefore elicits antibodies; therefore it would be obvious to detect a different antibody to determine the presence of a NDV vaccine strain or wild-type infection.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to test for the presence of an antibody against a protein not expressed by the recombinant DNA vaccine to distinguish them from animals vaccinated with different vaccine compositions or having wild-type infections wherein other immunogenic proteins are expressed. The person of ordinary skill in the art would have been motivated to use a method of detecting antibodies present in the different types of vaccines because Taylor teaches the importance of detecting natural infection versus antibodies from vaccination, and reasonably would have expected success because of the teachings of Taylor.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the method defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

September 21, 2007

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